





Sheet 1 of 6

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| <b>Form PTO-1449 Modified</b><br><br>List of Patent and Publications<br>Cited by Applicant<br>(Use several sheets if necessary)<br><br>U.S. Department of Commerce<br>Patent and Trademark Office |    | Docket No.<br>TJU0006-101  | Serial No.<br>10/695,578  |
|   |    | Applicant<br><br>Scott A. Waldman et al.   |                           |
|   |    | Filing Date<br>10/27/2003  | Group<br>To Be Determined |
| <b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>   |    |  |                           |
|   | AA | Almenoff et al., "Induction of heat-stable enterotoxin receptor activity by a human Alu repeat," <i>J. Biol. Chem.</i> , 1994, 269(24), 16610-16617  |                           |
|   | AB | Berd et al., "Immunization with Haptenized, Autologous Tumor Cells Induces Inflammation of Human Melanoma Metastases", <i>Cancer Res.</i> , 1991, 51, 2731-2734  |                           |
|   | AC | Berd et al., "Induction of Cell-mediated Immunity to Autologous Melanoma Cells and Regression of Metastases after Treatment with a Melanoma Cell Vaccine Preceded by Cyclophosphamide", <i>Cancer Res.</i> , 1986, 46, 2572-2577 |                           |
|   | AD | Carrithers et al., "Escherichia coli heat-stable toxin receptors in human colonic tumors," <i>Gastroenterology</i> , 1994, 107, 1653-1661  |                           |
|   | AE | Carrithers et al., "Escherichia coli heat-stable enterotoxin receptors. A novel marker for colorectal tumors," <i>Diseases Colon &amp; Rectum</i> , 1996, 39(2), 171-181   |                           |
|   | AF | Francis et al., Peptide Vaccines Based on Enhanced Immunogenicity of Peptide Epitopes Presented with T-Cell Determinants or Hepatitis B Core Protein", <i>Methods in Enzymol.</i> , 1989, 178, 659-676                           |                           |
|   | AG | MacLean et al., "Immunization of breast cancer patients using a synthetic sialyl-Tn glycoconjugate plus Detox adjuvant", <i>Cancer Immunol. Immunother.</i> , 1993, 36, 215-222  |                           |
|   | AH | Miller et al., "The Induction of Hapten-Specific T Cell Tolerance by Using Hapten-Modified Lymphoid Cells", <i>J. Immunol.</i> , 1976, 117(5:1), 1519-1526   |                           |
|   | AI | Rudner et al., "Regulation of cell signaling by the cytoplasmic domains of the heat-stable enterotoxin receptor: Identification of autoinhibitory and activating motifs", <i>Proc. Natl. Acad. Sci.</i> , 1995, 92, 5169-5173    |                           |
|   | AJ | Sad et al., "Bypass of carrier-induced epitope-specific suppression using a T-helper epitope", <i>Immunology</i> , 1992, 76, 599-603   |                           |
|   | AK | Waldman et al., "Immunoaffinity Purification of Soluble Guanylyl Cyclase", <i>Methods Enzymol.</i> , 1991, 195, 391-396  |                           |
| <b>EXAMINER</b>   |    | <b>DATE CONSIDERED</b> 8.25.06   |                           |

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|---|----|--------------|----------|--------------------------------|-------------|------------------|--|
|   |    |              |          | TJU0006-101                    |             | 10/695,578       |  |
|   |    |              |          | Applicant                      |             |                  |  |
|   |    |              |          | Scott A. Waldman et al.        |             |                  |  |
|   |    |              |          | Filing Date                    |             | Group            |  |
|   |    |              |          | 10/27/2003                     |             | To Be Determined |  |
| <b>U. S. PATENT DOCUMENTS</b>   |    |              |          |                                |             |                  |  |
| Examiner Initial  |    | Document No. | Date     | Name                           | Class       | Subclass         |  |
|    | AL | 4,022,878    | 05/10/77 | Gross                          | 424         | 1.5              |  |
|   | AM | 4,329,281    | 05/11/82 | Christenson et al.             | 260         | 112 B            |  |
|   | AN | 4,526,716    | 07/02/85 | Stevens                        | 260         | 112.5 R          |  |
|   | AO | 4,736,866    | 04/12/88 | Leder et al.                   | 800         | 1                |  |
|   | AP | 4,873,191    | 10/10/89 | Wagner et al.                  | 435         | 172.3            |  |
|   | AQ | 4,945,050    | 07/31/90 | Sanford et al.                 | 435         | 172.1            |  |
|   | AR | 5,017,487    | 05/21/91 | Stunnenberg et al.             | 435         | 172.3            |  |
|   | AS | 5,037,645    | 08/06/91 | Strahilevitz                   | 424         | 85.8             |  |
|   | AT | 5,112,606    | 05/12/92 | Shiosaka et al.                | 530         | 389.2            |  |
|   | AU | 5,352,775    | 10/04/94 | Albertsen et al.               | 536         | 23.1             |  |
|   | AV | 5,518,888    | 05/21/96 | Waldman                        | 435         | 7.23             |  |
|   | AW | 5,601,990    | 02/11/97 | Waldman                        | 435         | 7.23             |  |
| <b>FOREIGN PATENT DOCUMENTS</b>   |    |              |          |                                |             |                  |  |
| Examiner Initial  |    | Document No. | Date     | Country                        | Translation |                  |  |
|   |    |              |          |                                | YES         | NO               |  |
|    | AX | WO 90/11092  | 10/04/90 | PCT                            | X           |                  |  |
|    | AY | WO 95/11694  | 05/04/95 | PCT                            | X           |                  |  |
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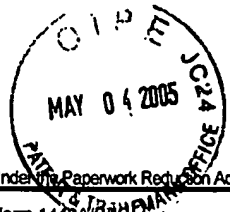
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|   | Applicant<br>Scott A. Waldman et al. |                           |
|   | Filing Date<br>10/27/2003            | Group<br>To Be Determined |

## U. S. PATENT DOCUMENTS

| Examiner Initial |    | Document No. | Date    | Name           | Class | Subclass |
|------------------|----|--------------|---------|----------------|-------|----------|
| <i>SA</i>        | AA | 5,518,888    | 5/21/96 | Waldman et al. | 435   | 7.23     |
|                  | AB | 5,601,990    | 2/11/97 | Waldman et al. | 435   | 7.23     |
|                  | AC | 5,731,159    | 3/24/98 | Waldman et al. | 435   | 7.23     |
|                  | AD | 5,879,656    | 3/9/99  | Waldman et al. | 424   | 149      |
|                  | AE |              |         |                |       |          |
|                  | AF |              |         |                |       |          |
|                  | AG |              |         |                |       |          |
|                  | AH |              |         |                |       |          |
|                  | AI |              |         |                |       |          |
|                  | AJ |              |         |                |       |          |

## FOREIGN PATENT DOCUMENTS

| Examiner Initial   |    |  |  |                         |  |
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|                    | AK |  |  |                         |  |
|                    | AL |  |  |                         |  |
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|                    | AO |  |  |                         |  |
| EXAMINER <i>SA</i> |    |  |  | DATE CONSIDERED 8.25.06 |  |



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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 6

## Complete if Known

|                        |                           |
|------------------------|---------------------------|
| Application Number     | 10/695,578                |
| Filing Date            | October 27, 2003          |
| First Named Inventor   | Scott A. Waldman          |
| Art Unit               | To Be Determined          |
| Examiner Name          | To Be Determined          |
| Attorney Docket Number | TJU0006-101 (WAL_SCO_005) |

## U.S. PATENT DOCUMENTS

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Document Number                            | Publication/Issue Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|------------------------|--------------------------|--|--------------------------------------|--|---|
|                        |                          | Number - Kind Code <sup>2</sup> (if known) |                                      |  |   |
| SA<br>I                | BA                       | US-5,273,745                               | 12-1993                              | Waldman et al.                                     |   |
|                        | BB                       | US-5,484,596                               | 11-1993                              | Hanna et al.                                       |   |
|                        | BC                       | US-5,237,051                               | 08-1993                              | Garbers et al.                                     |   |
|                        |                          | US-  |                                      |  |   |
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## FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication<br>Date/Filing Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>3</sup> |
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|                        |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |   |   |  |                |
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| Examiner<br>Signature |  | Date<br>Considered | 8-26-06 |
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**


(Use as many sheets as necessary)

Sheet 5 of 6

**Complete if Known**

|                        |                           |
|------------------------|---------------------------|
| Application Number     | 10/695,578                |
| Filing Date            | October 27, 2003          |
| First Named Inventor   | Scott A. Waldman          |
| Art Unit               | To Be Determined          |
| Examiner Name          | To Be Determined          |
| Attorney Docket Number | TJU0006-101 (WAL_SCO_005) |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials *   | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|---|-----------------------|---|----------------|
|  | BD                    | Banchereau et al., "Immune and clinical responses in patient with metastatic melanoma to CD34+ progenitor-derived dendritic cell vaccine," <i>Cancer Research</i> (2001) 61:6451-6458.  |                |
|   | BE                    | Bellone et al., "Cancer immunotherapy: synthetic and natural peptides in the balance," <i>Immunology Today</i> (1999) 20(10):457-462.   |                |
|   | BF                    | Carrithers et al., "Escherichia coli heat-stable toxin receptors in human colonic tumors," <i>Gastroenterology</i> (1994) 107:1653-1661.  |                |
|   | BG                    | Celis et al., "Identification of potential CTL epitopes of tumor-associated antigen MAGE-1 for five common HLA-A alleles," <i>Molecular Immunology</i> (1994) 31(18):1423-1430.   |                |
|   | BH                    | Disis et al., "Peptide-based, but not whole protein, vaccines elicit immunity to HER-2/neu, oncogenic self-protein," <i>J. of Immunology</i> (1996) 156:3151-3158.  |                |
|   | BI                    | Foon et al., "Clinical and immune responses in resected colon cancer patients treated with anti-idiotypic monoclonal antibody vaccine that mimics the carcinoembryonic antigen," <i>Journal of Clinical Oncology</i> (1999) 17(9):2889-2895.                    |                |
|   | BJ                    | Herbert et al., <i>The Dictionary of Immunology</i> , Academic Press, 4th ed. (1995).   |                |
|   | BK                    | Greenspan et al., "Defining epitopes: It's not as easy as it seems," <i>Nature Biotechnology</i> (1999) 7:936-937.  |                |
|   | BL                    | Gura "Systems for identifying new drugs are often faulty," <i>Science</i> (1997) 278:1041-1042.   |                |
|   | BM                    | Mallo et al., "Expression of the Cdx1 and Cdx2 homeotic genes leads to reduced malignancy in colon cancer-derived cells," <i>J. Biological Chemistry</i> (1998) 273(22):14030-14036.  |                |
|   | BN                    | Nelson et al., <i>J. Nat'l. Can. Ins.</i> (1996) 88(8):468-488.   |                |

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| Examiner Signature |  | Date Considered | 8-26-06 |
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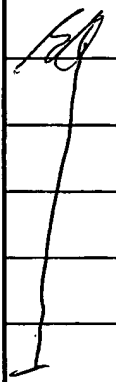
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| Substitute for form 1449B/PTO                            |   | <b>Complete if Known</b>      |                           |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   | <i>Application Number</i>     | 10/695,578                |
|  |   | <i>Filing Date</i>            | October 27, 2003          |
|  |   | <i>First Named Inventor</i>   | Scott A. Waldman          |
|  |   | <i>Art Unit</i>               | To Be Determined          |
|  |   | <i>Examiner Name</i>          | To Be Determined          |
| (Use as many sheets as necessary)                        |   | <i>Attorney Docket Number</i> | TJU0006-101 (WAL_SCO_005) |
| Sheet  | 6 | of                            | 6                         |

| NON PATENT LITERATURE DOCUMENTS  |                       |   |                |
|--|-----------------------|---|----------------|
| Examiner Initials *  | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|  | BO                    | Reynolds et al., "Vaccine-induced CD8+ T-cell responses to MAGE-3 correlate with clinical outcome in patients with melanoma," <i>Clinical Cancer Research</i> (2003) 9:657-662.   |                |
|  | BP                    | Singh et al., "Isolation and expression of a guanylate cyclase-coupled heat stable enterotoxin receptor cDNA from a human colonic cell line," <i>Biochem. Biophys. Res. Comm.</i> (1991) 179(3):1455-1463.  |                |
|  | BQ                    | Smith "Cancer and the immune system," <i>Pediatr Clin North Am.</i> (1994) 41(4) 841-850.   |                |
|  | BR                    | Spitler "Cancer vaccines: the interferon analogy," <i>Cancer Biotherapy</i> (1995) 10:1-3.  |                |
|  | BS                    | Welzien HU "Renaissance for hapten-specific T lymphocytes: implications for basic and applied research," <i>Z Naturforsch [C]</i> (1992) 47(5-6):323-328.   |                |
|  | BT                    | Miller et al., "Improved survival of patients with Melanoma with an antibody response to immunization of a polyvalent melanoma vaccine," <i>Cancer</i> (1995) 75(2):495-502.  |                |
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